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Approved Drugs

• The Food and Drug Administration (FDA) has approved **Beleodaq® (belinostat)** (Spectrum Pharmaceuticals, Inc., www.sppirx.com) for the treatment of patients with peripheral T-cell lymphoma (PTCL). It is intended for patients whose disease returned after treatment or who did not respond to previous treatment.

• Genentech (www.gene.com) announced that the FDA has approved **Avastin® (bevacizumab solution for intravenous infusion)** for the treatment of persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

• The FDA has approved a new indication for Bayer HealthCare's (www.bayer.com) **Gadavist® (gadobutrol) injection** for intravenous use with MRI of the breast to assess the presence and extent of malignant breast disease.

• The FDA expanded the approved use of **Imbruvica® (ibrutinib)** (Janssen Biotech, www.janssenbiotech.com) to treat patients with chronic lymphocytic leukemia (CLL) who carry a deletion in chromosome 17 (17p deletion), which is associated with poor responses to standard treatment for CLL.

• **Lymphoseek (technetium Tc 99m tilmanocept) Injection** (Navidea Biopharmaceuticals, www.navidea.com) has received FDA approval as an agent to guide sentinel lymph node biopsy procedures, specifically in head and neck cancer patients with squamous cell carcinoma of the oral cavity.

• The FDA approved **Zydelig™ (idelalisib)** (Gilead Sciences, Inc., www.gilead.com) to treat patients with three types of blood cancers. Zydelig is being granted traditional approval to treat patients whose CLL has returned. Used in combination with Rituxan (rituximab), Zydelig is to be used in patients for whom Rituxan alone would be considered appropriate therapy due to other existing medical conditions. The FDA is also granting Zydelig accelerated approval to treat patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) and relapsed small lymphocytic lymphoma (SLL), another type of non-Hodgkin lymphoma. Zydelig is intended to be used in patients who have received at least two prior systemic therapies.

Drugs in the News

• AbbVie, Inc. (www.abbvie.com) announced that the FDA has granted orphan drug designation to **ABT-414**, an anti-epidermal growth factor receptor antibody drug conjugate, which is being evaluated for safety and efficacy in patients with glioblastoma multiforme.

• Mirati Therapeutics, Inc. (www.mirati.com) announced that **mocetinostat**, a spectrum selective HDAC inhibitor, has been granted orphan drug designation by the FDA as a treatment for myelodysplastic syndrome (MDS).

Approved Devices

• Varian Medical Systems (www.varian.com) announced that it has received FDA 510(k) clearance for the **Calypso® soft tissue Beacon® transponder**, which can help enhance the precision of radiotherapy and radiosurgery treatments for cancer.

• IBA (Ion Beam Applications SA, www.iba-worldwide.com) announced that it has received FDA 510(k) clearance for its **Compact Gantry Beam Line**. **Proteus® ONE** is a single-room proton therapy system, which is smaller, less expensive, faster to install, and encompasses the latest in targeted proton therapy technologies.

• **ProctiGard™** (Access Pharmaceuticals, Inc., www.accesspharma.com), a novel treatment for symptomatic management of rectal mucositis, has received FDA 510(k) clearance.

Genetic Tests and Assays in the News

• Exact Sciences Corp. (www.exactsciences.com) announced that the FDA has approved **Cologuard**, the first stool-based colorectal screening test that detects the presence of red blood cells and DNA mutations that may indicate the presence of certain kinds of abnormal growths that may be cancers such as colon cancer or precursors to cancer.